

REMARKS

This paper is filed in response to the official action dated April 20, 2004 (hereafter, the "official action"). This paper is timely filed as it is accompanied by a petition for an extension of time to file in the second month and a check covering the requisite small-entity extension fee.

Claims 5-10, 19-23, 34, and 37-39 are pending in this application. Claim 35 has been withdrawn from consideration. By the foregoing amendments, claims 5, 10, 22, and 23 have been amended. Support for the amendments may be found throughout the application and in the claims as originally filed. No new matter has been added.

Claims 5-10, 19-23, 34, and 37-39 remain rejected under 35 U.S.C. §112, first paragraph, as assertedly not enabled. Claims 5-7, 9, 10, 19-23, and 38-39 have been rejected under 35 U.S.C. §102(b) as assertedly being anticipated by Sal'kova *et al.*, Appl. Biochem. Microbiol., 17(2):219-224 (1981) ("Sal'kova"). Claims 5, 9, 10, 19-23, 34, 37, and 39 have been rejected under 35 U.S.C. §102(b) as assertedly being anticipated by Archer *et al.*, J. Anim. Sci., 33(6):1327-1331 (1971) ("Archer"). Finally, claims 5-10, 19-23, 34, and 36-39 have been rejected under 35 U.S.C. §103 as assertedly being obvious over Archer in view of McMurry, Organic Chemistry, p.385 (1992) ("McMurry").

The various bases for the claim rejections are addressed below in the order presented in the official action. Reconsideration of the application, as amended and in view of the following remarks, is solicited.

CLAIM REJECTIONS – 35 U.S.C. §112, FIRST PARAGRAPH

Claims 5-10, 19-23, 34, and 37-39 remain rejected under 35 U.S.C. §112, first paragraph, for lack of enablement commensurate in scope with the claims. The applicants respectfully submit that these rejections are improper and should be withdrawn.

The examiner acknowledged that the specification is "enabling for a method for extracting the crude epicuticular layer of plants or plant parts via exposure to a solvent (and the corresponding crude product obtained therefrom) which has some activity against HSV-1, [but asserted that the specification] does not reasonably provide enablement for the broad recitation of 'an antiviral substance' purified from any plant." See official action at pages 2-3.

In response, the applicants respectfully submit that no pending claim recites a purified antiviral substance. "The invention that one skilled in the art must be enabled to make and use is that defined by the *claim(s)* of the particular application or patent." See MPEP § 2164 (emphasis added). Therefore, the rejection of claims 5-10, 19-23, 34, and 37-39 under 35 U.S.C. §112, first paragraph, for not providing a purified antiviral substance from an apple (or tomato) plant or plant part is improper and should be withdrawn.

The examiner also stated that "there is some indication in the Instant specification that apple, avocado, cabbage, grape, and tomato produced *some* inhibition towards HSV-1. [However,] Applicant[s] did not disclose what parts of the plants actually produced this 'anti-viral substance'." See official action at page 3.

In response, the applicants respectfully submit that the antiviral preparations are derived from the cuticular and epicuticular layers of a plant or plant part, not a plant or plant part *per se*. It is the applicants' discovery of anti-viral compounds in the cuticular and epicuticular layers of a wide variety of plants and plant parts (including apple and tomato plants and plant parts as recited by the pending claims) disclosed in the application-as-filed, that led to the applicants' invention. Moreover, the applicants respectfully submit that the specification identifies exemplary plant parts such as fruits, flowers, leaves, roots, stems, and bark, that contain anti-viral substances in their cuticular and epicuticular layers. See application at page 8, lines 23-29. Thus, the applicants have disclosed that the antiviral compounds are found in (1) the cuticular and/or epicuticular layers of a (2) variety of plants (including apple and tomato plants as recited by the pending claims), and (3) parts thereof. Therefore, the rejection of claims 5-10, 19-23, 34, and 37-39 under 35 U.S.C. §112, first paragraph, for not disclosing the specific parts of the plants is improper and should be withdrawn.

The examiner also asserted that the claims are not enabled because examples 61 and 64 of the specification, which are apple plant part extracts, exhibit different *in vitro* anti-HSV activity values. See official action at page 3.

The applicants respectfully submit that both examples demonstrate anti-HSV activity; therefore, neither example constitutes an inoperative embodiment. Further, the difference in relative activity levels present no difficulty to those of ordinary skill in the art, as such individuals expect to use routine procedures to optimize dose on an individual basis, taking

into account not only the activity levels of the therapeutic, but also other routine variables known in the art such as weight, general health, gender, and age. Thus, the rejection of claims 5-10, 19-23, 34, and 37-39 under 35 U.S.C. §112, first paragraph, because samples 62 and 64 have different inhibitory activities is improper and should be withdrawn.

The examiner also asserted that “it is *a priori* unpredictable to extrapolate … to other viruses such as tobacco mosaic, HIV or the flu virus for example,” based on the different inhibitory activities of samples 61 and 64. *See* official action at page 3. The examiner further stated that consequently “[e]ven the most skilled of artisans would need to perform expensive, time consuming trial and error protocols in order to determine if the claims are functional within their broad scope, constituting *undue experimentation*.¹” *See* official action at page 3 (emphasis in original).

The applicants respectfully submit that the application-as-filed contains data illustrating the efficacy of antiviral preparations prepared from apple and tomato plants and plant parts. In this regard, the examiner’s attention is directed to samples 61, 64, and 65, which demonstrate the anti-HSV inhibitory activity of such anti-viral preparations. The applicants further direct the examiner’s attention to their assertion that such anti-viral preparations possess an anti-influenza activity. *See* application at page 16, line 28 – page 17, line 3. Notably, no samples derived from apple or tomato plants or plant parts show an absence of antiviral activity.

The applicants respectfully submit that no further demonstration of anti-viral activity for the antiviral preparations is required. Moreover, because a variety of assays for assessing the antiviral activity of compounds are known to those of ordinary skill in the art, *any remaining experimentation would be minimal and, more importantly, routine*. Thus, the facts of this case do not provide a basis for concluding that undue experimentation would be required to practice the full scope of the invention. Therefore, the rejection of claims 5-10, 19-23, 34, and 37-39 as not enabled under 35 U.S.C. §112, first paragraph, is improper and should be withdrawn.

CLAIM REJECTIONS -- 35 U.S.C. §102

It is well-established that each and every limitation of a claimed invention must be present in a single prior art reference in order for anticipation to occur. *See*, for example, *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1349 (Fed. Cir. 1998). The standard for

anticipation is one of strict identity. This standard has not been satisfied with respect to the pending claims, as amended herein.

Claims 5-7, 9, 10, 19-23, and 38-39

Claims 5-7, 9, 10, 19-23, and 38-39 have been rejected under 35 U.S.C. §102(b) as being anticipated by Sal'kova. The applicants respectfully traverse the rejections of claims 5-7, 9, 10, 19-23, and 38-39 as being anticipated by Sal'kova.

Sal'kova discloses substances capable of inhibiting and suppressing the oxidation of farnesene, which were isolated from the coating of an apple fruit by extraction with hexane. Sal'kova does not disclose formulating an antiviral preparation with a pharmaceutically acceptable carrier to form a pharmaceutical composition, as recited by claims 5-7, 9, 10, 19-23, and 38-39. Moreover, Sal'kova does not disclose or suggest any antiviral activity for the apple fruit extract. Accordingly, the rejection of claims 5-7, 9, 10, 19-23, and 38-39 as being anticipated by Sal'kova should be withdrawn.

Claims 5, 9, 10, 19-23, 34, 37, and 39

Claims 5, 9, 10, 19-23, 34, 37, and 39 have been rejected under 35 U.S.C. §102(b) as being anticipated by Archer. The applicants respectfully traverse the rejections of claims 5, 9, 10, 19-23, 34, 37, and 39 as being anticipated by Archer.

Archer discloses the levels of undesirable Kelthane contaminants, which are used as insecticides, in apples, including whole apples, the pomace (skins and seeds), pulp, and juice. Archer does not disclose formulating an antiviral preparation with a pharmaceutically acceptable carrier to form a pharmaceutical composition, as recited by claims 5, 9, 10, 19-23, 34, 37, and 39. Moreover, Archer does not disclose or suggest any antiviral activity for the apple fruit extract. Accordingly, the rejection of claims 5, 9, 10, 19-23, 34, 37, and 39 as being anticipated by Archer should be withdrawn.

CLAIM REJECTIONS – 35 U.S.C. §103(a)

The applicants respectfully traverse the rejections of claims 5-10, 19-23, 34, and 36-39 as being obvious over Archer in view of McMurry.

A *prima facie* case of obviousness in view of multiple references requires satisfaction of three requirements. *First*, there must be some suggestion or motivation, either in the

references themselves, or in knowledge generally available to one of ordinary skill in the art, to modify a reference or to combine reference teachings. *Second*, there must be a reasonable expectation of success in doing so. *Third*, prior art references, when combined, must teach or suggest all of the claim limitations. See M.P.E.P. §2142. At least the third criteria has not been satisfied with respect to claims 5-10, 19-23, 34, and 36-39, as explained in more detail below.

The deficiencies of Archer have been previously addressed above. McMurry, alone or in combination with Archer, does not disclose formulating an antiviral preparation with a pharmaceutically acceptable carrier to form a pharmaceutical composition, as recited by all pending claims 5-10, 19-23, 34, and 36-39. Moreover, McMurry also does not suggest an antiviral activity for substances obtained from cuticular or epicuticular layers external to an epidermis of a plant or plant part. Accordingly, the rejection of claims 5-10, 19-23, 34, and 36-39 as being obvious over Archer in view of McMurry should be withdrawn, and therefore the non-elected species of tomato should be rejoined to the application.

CONCLUSION

It is respectfully submitted that this application is now in condition for allowance. Should the examiner wish to discuss the foregoing, or any matter of form or procedure in an effort to advance this application to allowance, she is respectfully invited to contact the undersigned attorney at the indicated telephone number.

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Respectfully submitted,

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